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#27

SEP 15 1992

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Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

Re: Patent Term Extension
Application for
U.S. Patent No. 4,344,949

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,344,949 issued August 17, 1982, which claims the human drug product Accupril, is eligible for extension of its patent term under 35 USC § 156. The period of extension has been determined to be two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of February 4, 1992. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (2,354) + 1,027 \\ &= 2,204 \text{ days}\end{aligned}$$

Since the regulatory review period began June 18, 1982, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on June 18, 1982, up to the issuance of the patent on August 17, 1982, is 60 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $2,414 - 60 = 2,354$ days. No determination of a lack of due diligence was made.

The two year limitation of 35 USC § 156 (g) (6) (C) applies in the present situation because: (1) the patent was issued before the date of enactment (September 24, 1984) of 35 USC § 156; (2) the date an exemption under subsection 505 (i) of the Federal Food, Drug and Cosmetic Act involving the approved product became effective (June 18, 1982) was before the date of enactment; and, (3) the date the new drug application was approved (November 19, 1991) was after the date of enactment. Since the period of extension calculated under 35 USC § 156 (c) for the patent cannot exceed two years under 35 USC § 156 (g) (6) (C), the period of extension will be for two years.

The 14 year exception of 35 USC § 156 (c) (3) does not operate to further reduce the period determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,344,949 a certificate of extension, under seal, for a period of two years.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,344,949
Granted:	August 17, 1982
Applicant:	Hoefle et al
Owner of Record:	Warner - Lambert Company
Title:	SUBSTITUTED ACYL DERIVATIVES OF 1,2,3,4 - TETRAHYDROISOQUINOLINE - 3 - CARBOXYLIC ACIDS
Classification:	514/307
Product Trade Name:	Accupril
Term Extended:	Two years

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Accupril

FDA Docket No.: 91E - 0492